

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

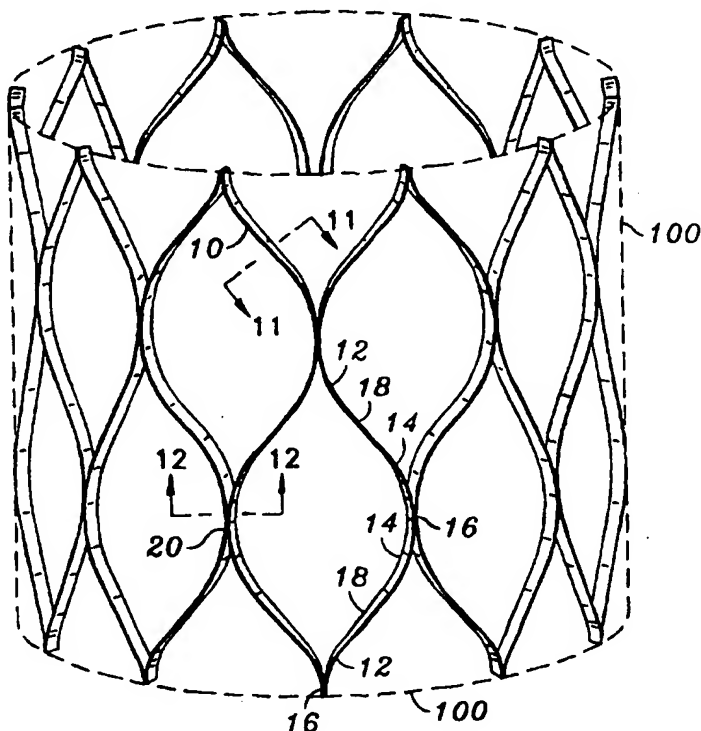
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|--|---|--|
| (51) International Patent Classification ⁶ : A61F 2/04 | A1 | (11) International Publication Number: WO 97/25000 (43) International Publication Date: 17 July 1997 (17.07.97) |
| <p>(21) International Application Number: PCT/US97/00033</p> <p>(22) International Filing Date: 3 January 1997 (03.01.97)</p> <p>(30) Priority Data: 08/582,943 4 January 1996 (04.01.96) US</p> <p>(71)(72) Applicant and Inventor: CHUTER, Timothy, A., M. [US/US]; 1534 Plaza Lane, Burlingame, CA 94010 (US).</p> <p>(74) Agent: LANE, William, G.; Law Offices of William G. Lane, Suite 500, 18400 Von Karman Avenue, Irvine, CA 92612 (US).</p> | <p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p> | |

(54) Title: **FLAT WIRE STENT**

(57) Abstract

The present invention concerns an improved stent in which the limbs (10) have been fabricated from a medium having a cross-sectional profile in which at least one segment is flat and straight, whereby the stent is provided with improved expansion characteristics.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | |
|----|--------------------------|----|--|----|--------------------------|
| AM | Armenia | GB | United Kingdom | MW | Malawi |
| AT | Austria | GE | Georgia | MX | Mexico |
| AU | Australia | GN | Guinea | NE | Niger |
| BB | Barbados | GR | Greece | NL | Netherlands |
| BE | Belgium | HU | Hungary | NO | Norway |
| BF | Burkina Faso | IE | Ireland | NZ | New Zealand |
| BG | Bulgaria | IT | Italy | PL | Poland |
| BJ | Benin | JP | Japan | PT | Portugal |
| BR | Brazil | KE | Kenya | RO | Romania |
| BY | Belarus | KG | Kyrgyzstan | RU | Russian Federation |
| CA | Canada | KP | Democratic People's Republic of Korea | SD | Sudan |
| CF | Central African Republic | KR | Republic of Korea | SE | Sweden |
| CG | Congo | KZ | Kazakhstan | SG | Singapore |
| CH | Switzerland | LI | Liechtenstein | SI | Slovenia |
| CI | Côte d'Ivoire | LK | Sri Lanka | SK | Slovakia |
| CM | Cameroon | LR | Liberia | SN | Senegal |
| CN | China | LT | Lithuania | SZ | Swaziland |
| CS | Czechoslovakia | LU | Luxembourg | TD | Chad |
| CZ | Czech Republic | LV | Latvia | TG | Togo |
| DE | Germany | MC | Monaco | TJ | Tajikistan |
| DK | Denmark | MD | Republic of Moldova | TT | Trinidad and Tobago |
| EE | Estonia | MG | Madagascar | UA | Ukraine |
| ES | Spain | ML | Mali | UG | Uganda |
| FI | Finland | MN | Mongolia | US | United States of America |
| FR | France | MR | Mauritania | UZ | Uzbekistan |
| GA | Gabon | | | VN | Viet Nam |

FLAT WIRE STENT

FIELD OF THE INVENTION

5 The present invention relates to an improved "stent" for placement in corporeal lumens. More particularly, this invention relates to an improved stent in which the limbs have been fabricated from a medium having a cross sectional profile in which at least one segment is straight, whereby the stent is provided with improved expansion characteristics.

10

BACKGROUND OF THE INVENTION

 The term "stent" generally refers to a prosthesis which can be introduced into a corporeal lumen and expanded to support that lumen or attach a conduit to the
15 inner surface of that lumen.

 A number of prior art references are available in the art, each of which references are directed to some specific discreet elements of the system which are described and claimed in the present invention, however, none of which is directed
20 to the totality of the combination, or its use and function in the manner described and claimed herein.

 The following prior art references are known to the inventor:

25 U.S. Patent No. 4,580,568, which issued to Gianturco on April 8, 1986, discloses an endovascular stent formed of stainless steel wire which is arranged in a closed zig-zag pattern;

U.S. Patent No. 4,733,665, which issued to Palmaz on March 29, 1988, relates to an expandable intraluminal vascular graft which is expanded within a blood vessel using an angioplasty balloon associated with a catheter;

5 U.S. Patent No. 4,739,762, which issued to Palmaz on April 26, 1988, teaches an expandable intraluminal graft for use within a body passageway or duct which is particularly useful for repairing blood vessels which have been narrowed or occluded by disease;

10 U.S. Patent No. 4,830,003, which issued to Wolff et al. on May 16, 1989, which issued to Wolff et al. on May 16, 1989, discloses a cylindrical shaped stent useful to prevent arterial acute closure which is formed of longitudinal wires of bio-compatible material which wires have been welded together in pairs at alternate ends with each pair of wires bent into a V-section. The wires are formed into a cylinder
15 which is welded closed in order to form the stent;

U.S. Patent No. 5,104,404, which issued to Wolff on April 14, 1992, teaches an intravascular stent which is applied within the peripheral or coronary arteries of a living animal or a human being in order to return patency after a
20 balloon angioplasty. The stent taught in this reference is an articulated separate stent comprising at least two segments each of which segments have a generally tubular shape and a hinge means extending between and connecting adjoining stent segments;

25 U.S. Patent No. 5,019,090, which issued to Pinchuk on May 28, 1991, relates to radially expandable stents which include a plurality of adjacent generally circumferential sections which are substantially axially positioned with respect to each other;

U.S. Patent No. 4,886,062, which issued to Wiktor on December 12, 1989, discloses a device which is to be used as a vascular stent comprising a cylindrical open ended wire made of a low memory metal, which is characterized by its ability to be expanded radially to a larger diameter after initial implantation, along with a
5 means for causing said stent to expand to a larger diameter and a method for transporting, positioning and implantation of such stent;

U.S. Patent No. 5,370,683, which issued to Fontaine on December 6, 1994, is directed to a vascular stent for reducing hemodynamic disturbances caused by angioplasty, said stent being formed from a single filament of low memory biocompatible material having a series of U-shaped bends. The filament is wrapped about a
10 mandril in a circular fashion in order to align the curved portions of each bend which may then be connected;

U.S. Patent No. 5,226,913, which issued to Pinchuk on July 13, 1993, teaches a radially expandable stent which includes a plurality of adjacent generally circumferential sections that are substantially axially positioned with respect to each other, wherein at least one of the generally circumferential sections has an expandable segment which imparts a circumferential and radial expandability to the stent;
15

U.S. Patent No. 4,913,141, which issued to Hillstead on April 3, 1990, relates to a stent delivery system for routing the stent to a defined position within a subject's blood vessel;
20

U.S. Patent No. 5,133,732, which issued to Wiktor on July 28, 1992, discloses a stent for implantation into a body vessel comprising a cylindrical stent body which has been coiled from a generally continuous wire which has been imparted with a deformable zig-zag structure;
25

U.S. Patent No. 5,135,536, which issued to Hillstead on August 4, 1994, is directed to a stent for reinforcing a vessel wall which is constructed from a single elongated wire. The wire has been first bent into a series of tight bends and then rolled around a mandrel in order to create junctions of wire which are permanently adhered. The completed stent forms cylindrical shape which can be expanded from its initial diameter to a larger implanted diameter by the application of radial outward force from a balloon catheter;

U.S. Patent No. 4,655,771, which issued to Wallsten on April 7, 1987, teaches a prosthesis for transluminal implantation comprising a flexible tubular body which has a diameter that is variable by axial movement of the ends of the body relative to each other and which is composed of several individual rigid but flexible thread elements each of which extends in helix configuration with the centerline of the body as a common axis;

U.S. Patent No. 5,015,253, which issued to MacGregor on May 14, 1991, discloses a generally tubular stent that includes a non-woven structure formed by two or more generally helically shaped cylinders of stiff strand material where the strand material forming the non-woven structure is preferably secured together at attachment sites which allow the stent to be flexible and adjustable to meet various needs.

Most manifestations of the available prior art expand by the rotation of a structural element (limb) from a longitudinal orientation (parallel to the long axis of the stent) to a more transverse orientation. The limbs themselves change very little in shape. Stents, in which adjacent limbs are linked to form rings, spirals, or a series of linked rings, expand and contract by deformation of the structural elements in the immediate vicinity of the junction between limbs. In the case of self-expanding stents, the junctions serve as reservoirs of energy, which produce stent expansion.

sion. However, the isolation of mechanical stress to such small portions of the stent limits the expansion ratio and renders the stent less durable.

5 An example of this effect is the Gianturco Z-stent ('568). This stent is comprised of a single loop of wire, in which alternating straight segments wind back and forth between bends to form a crown. In the Gianturco Z-stent the junctional stresses can be diffused by increasing the radius of curvature at the bends; the larger the bend the more diffuse the stress. However, large radius bends limit the expansion ratio, because the bends take up more space than straight segments. Bending the limbs themselves does little to reduce the stress, because these bends are much less amenable to deformation than the bends between adjacent limbs. When the stent is compressed, the limbs soon meet along the outer curvatures of any bends. Any attempt to further collapse the stent by straightening the limbs is thwarted by the overlapping.

15

Other stents, which have no rings or spirals of alternating limbs and no fixed junctions between limbs are free of these problems, however, they also lack the expansile energy provided by junctional deformation, and therefore, tend to expand rather weakly. There are currently no self-expanding stents available in the prior art in which the relative positions of the joined limbs change as a result of deformation that is distributed over large segments of the limbs.

20

It is, therefore, an object of the present invention to provide for an improved stent which exhibits superior expansion characteristics over available prior art stents.

25

It is a further object of the present invention to provide for an improved stent in which the limb elements have been fabricated from a medium having a cross sectional profile in which at least one segment is flat and straight, which exhibits superior expansion characteristics over available prior art stents.

30

Lastly, it is an object of the present invention to provide for an improved stent which exhibits superior expansion characteristics over available prior art stents while at the same time avoiding the compression and deformation problems associated with other prior art stents.

These and other objects of the invention will become apparent from the following discussion of the invention.

SUMMARY OF THE INVENTION

The present invention provides for an improved stent in which the limbs have been fabricated from a medium having a cross sectional profile in which at least one segment is straight, whereby the stent is provided with improved expansion characteristics.

The construction and obvious advantages of the system provided for by the present invention will be more clearly understood from the following description of the various specific embodiments when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic representation depicting a single limb element according to the present invention.

Fig. 2 is a schematic representation depicting a single wire comprising four limb elements according to the present invention.

Fig. 3 is a schematic representation depicting a typical joints between adjacent limb elements in a stent which is comprised of a multiplicity of such limb elements.

5 Fig. 4A-4D is a schematic representation depicting the progressive compression of the joint between adjacent limb elements in a stent.

Fig. 5 is a schematic representation of a portion of a stent according to the present invention showing the relative geometry of the curved limb elements and the
10 joints between adjacent limb elements.

Fig. 6A is a schematic representation of the end of one limb of a stent according to the present invention depicting a barb which has been incorporated therein for anchoring the stent to a lumen wall.

15 Fig. 6B is a schematic representation of the end of a limb according to the present invention depicting serrations as an alternative for anchoring the stent to a lumen wall.

20 Fig. 7 is a schematic representation of the end of a limb according to the present invention depicting a hole for attachment of a delivery system release mechanism, or the like.

Fig. 8 is a schematic representation of an alternative embodiment of the present invention depicting a simplified series of limb elements which have been
25 attached to adjacent limb elements and the optional addition of a supplemental strut.

Fig. 9 is a schematic representation of an alternative embodiment of the present invention depicting a simplified series of limb elements which have been

attached to adjacent limb elements and the optional addition of two supplemental struts.

5

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to an improved stent in which the limbs have been fabricated from a material having a cross sectional profile in which at least one segment is straight, whereby the stent is provided with improved expansion characteristics as compared with available prior art stents.

10

The problems which have been experienced using prior art stents are solved in the present invention by creating the stent limbs from a material, generally a springy wire material, which has a cross-sectional profile in which at least one segment is flat and straight.

15

Two properties of flat wire are responsible for the principle advantages of this invention:

20

1. The flat surface of adjacent limb segments of the stent can be pressed together without generating the lateral forces that would otherwise cause them to overlap.

25

2. The mechanical stent limbs can be wide without taking up a large volume. The width of the limb makes it relatively rigid in the plane of its largest diameter, which also helps to prevent overlapping.

30

With reference to the attached figures, it can be seen from Figs. 1 and 5, that a repeating element of each limb 10 of the stent has two curves 12 and 14 of equal radius, equal length and opposite direction. The short straight segments 16 at the

ends of each limb element are parallel to one another. The mid-portion 18 lies between the two curved segments of each repeating element of the stent limb. Depending on the overall length of the stent, the same piece of wire may bend back and forth in a sinusoid wave, Fig. 2, to form a series of limb elements 10 down the length of the stent.

The short straight segments 16 of adjacent limbs are joined, either by welding, soldering, riveting, or gluing, as depicted in Figs. 3-9. A multiplicity of identical limb elements are joined in this way to form a cylindrical structure. With reference to Figs. 3 and 4A-4D, it can be seen that compression of the stent causes adjacent limb elements to be pressed against one another at their junctions 20. Further compression causes the curved portions 12 and 14 of adjacent limb elements to flatten progressively. The curves 12 and 14 thereby straighten and the stent assumes a smaller and smaller radius. When the constraining force is released, the stent expands through re-establishment of the curves 12 and 14.

The flat "wire" which is employed in the present invention can be made of any biocompatible material that is strong, durable and capable of elastic deformation.

The number of limb elements in each length of wire can be varied according to ratio of length to width required for the specific application in which the stent is to be employed. For example, an extended narrowing, as for example in a corporeal lumen such as an artery, a bile duct or an esophagus would require a stent that is much longer than it is wide. The individual wires in such a stent would, therefore, have many limbs elements 10, many bends 12 and 14, and many joints, since each wire would extend along the entire length of the stent. Alternatively, a stent which is used for anchoring a graft in a short segment of aorta would have very few limbs elements 10, perhaps only one, in each length of wire.

The radius and length of the curves 12 and 14 can be altered to effect the orientation of the section of the limb element that lies between the curves, the mid-section 18. In addition the mid-section 18 may vary in length as may be required for the particular application. The greater the angle described by each curve 12 and 14 in the limb element 10, the more transverse the orientation of the mid-section of the limb, the greater the shortening produced by stent expansion, the greater the flexibility of the stent, and the greater the resistance to compression by forces applied in direction of the stent radius. Lengthening the mid-section 10 of the limb element magnifies all of these effects.

With reference to Fig. 6A, an alternative embodiment of the end of a limb according to the present invention is shown wherein a barb can be added by notching 22 the edge of limb in order to provide a means for attachment of the limb to the inside of a corporeal lumen.

With reference to Fig. 6B, another alternative embodiment of the end of a limb according to the present invention is depicted, showing serrations 24 as a means for attachment of the limb to the inside of a corporeal lumen.

With reference to Fig. 7, anchor points for delivery system release mechanisms, or for graft attachment are provided for by drilling small holes 26 in the end of the limbs. The optional features weakens the limb, but have no effect on the structural integrity of the stent if they are placed in a section of the limb that is not between joints or connections 20.

The centrifugal expansile force generated by large stents can be increased by increasing the thickness of the wire. Alternatively, with reference to Figs. 8 and 9, optional struts 28 can be added to augment expansion alone, or augment both the expansile force by increasing the rigidity of the composite strut.

It will be further apparent to one skilled in this art that the improvements provided for in the present invention, while described with relation to certain specific physical embodiments also lend themselves to being applied in other physical arrangements not specifically provided for herein, which are nonetheless within the

5 spirit and scope of the invention taught here.

CLAIMS

I Claim:

1. An improved stent which is designed to provide superior expansion characteristics comprising limbs which have been fabricated from a medium having a cross sectional profile in which at least one segment is flat and straight.
2. An improved stent according to Claim 1 wherein the individual limbs are formed out of repeating elements, each of which is comprised of two curved portions having opposite directions of curvature, an intermediate straight, flat mid-portion connecting the two curved portions and a short, straight segment at each end.
3. An improved stent according to Claim 2 wherein the short, straight segments at each end of the repeating elements are joined to the short, straight segments of adjacent repeating elements.
4. An improved stent according to Claim 2 comprising a multiplicity of identical limbs which have been joined at each of the short, straight segments to the short segments of the adjacent limbs in order to form a cylindrical structure.
5. An improved stent according to Claim 2 wherein the stent is comprised of a multiplicity of wires which have been bent back and forth in a sinusoid wave pattern to form a series of limb elements down the length of the stent, each of which limb elements has been joined at the point of the short, straight segments to the short, straight segments of adjacent limb elements in order to form a cylindrical structure.

6. An improved stent according to Claim 2 wherein the overall length of the stent is a multiple of the overall diameter of the cylinder formed by joining the individual limb elements.

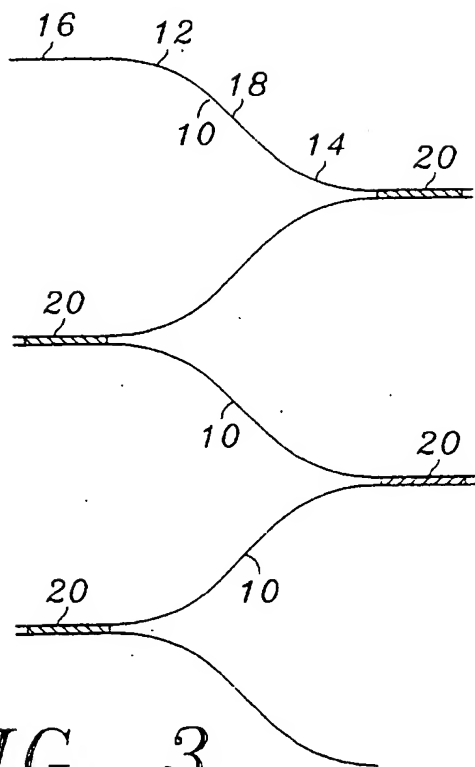
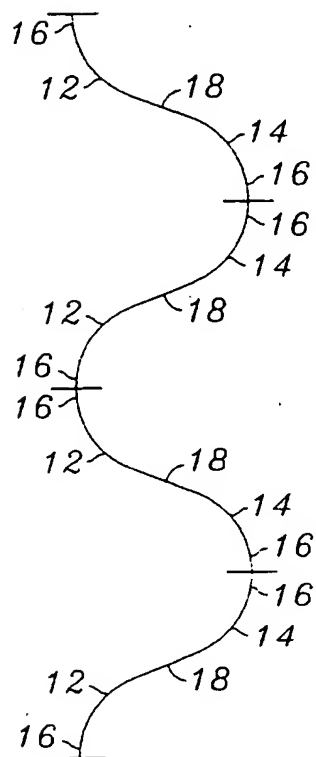
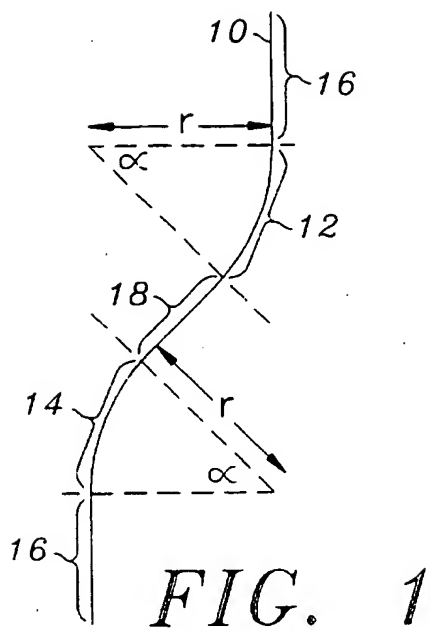
7. An improved stent according to Claim 2 wherein the end of each limb has been provided with a barb in order to provide a means of attachment of the stent to the inside of a corporeal lumen.

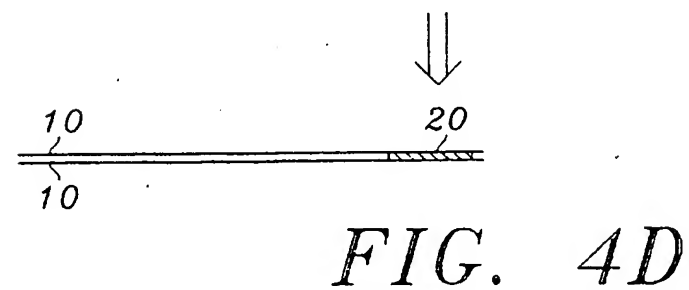
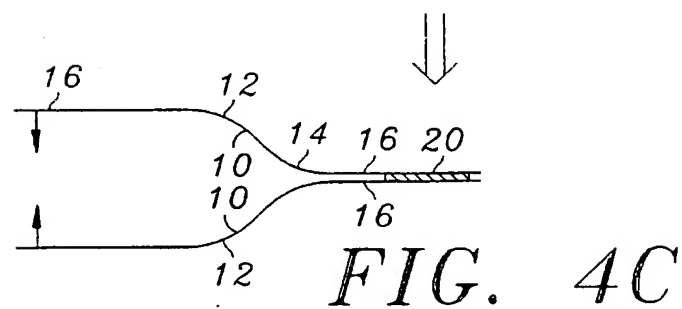
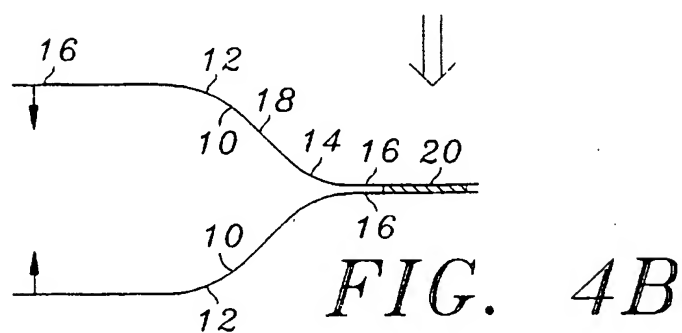
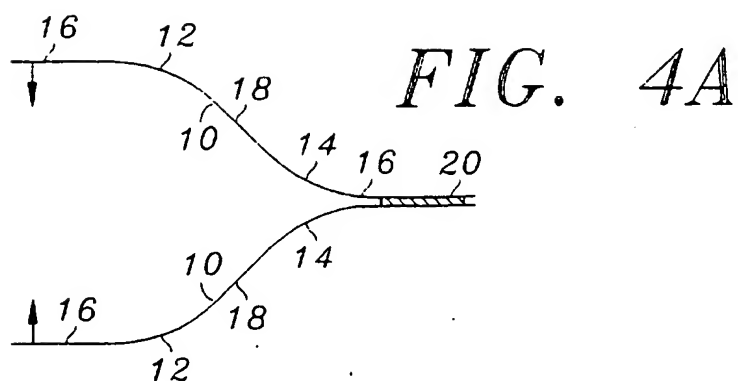
8. An improved stent according to Claim 2 wherein the end of each limb has been provided with a series of serrations in order to provide a means of attachment of the stent to the inside of a corporeal lumen.

9. An improved stent according to Claim 2 wherein the end of at least one limb comprising the stent has been provided with a hole as an anchor point for the attachment of a delivery system release mechanism.

10. An improved stent according to Claim 2 wherein the stent has been provided with at least one strut in order to augment expansion wherein the strut has been effectively attached at the point of attachment between the adjacent limb elements.

11. An improved stent according to Claim 2 wherein the stent has been provided with a multiplicity of struts to supplement each of the limb elements which have been effectively attached at both ends to the points of attachment between adjacent limb elements.





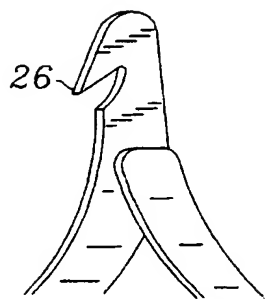


FIG. 6A

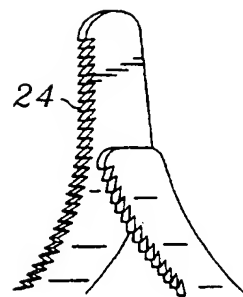


FIG. 6B

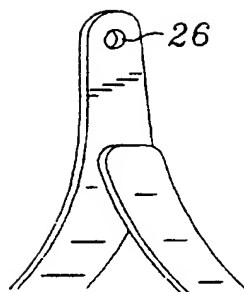


FIG. 7

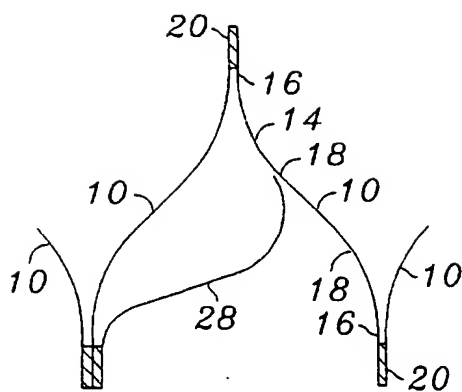


FIG. 8

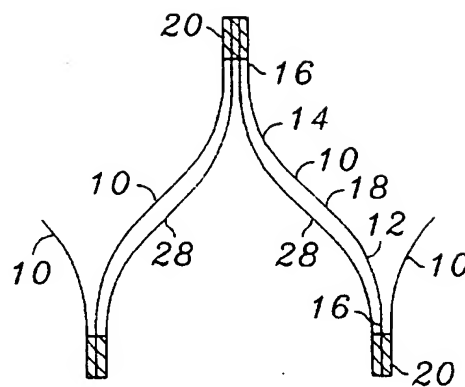


FIG. 9

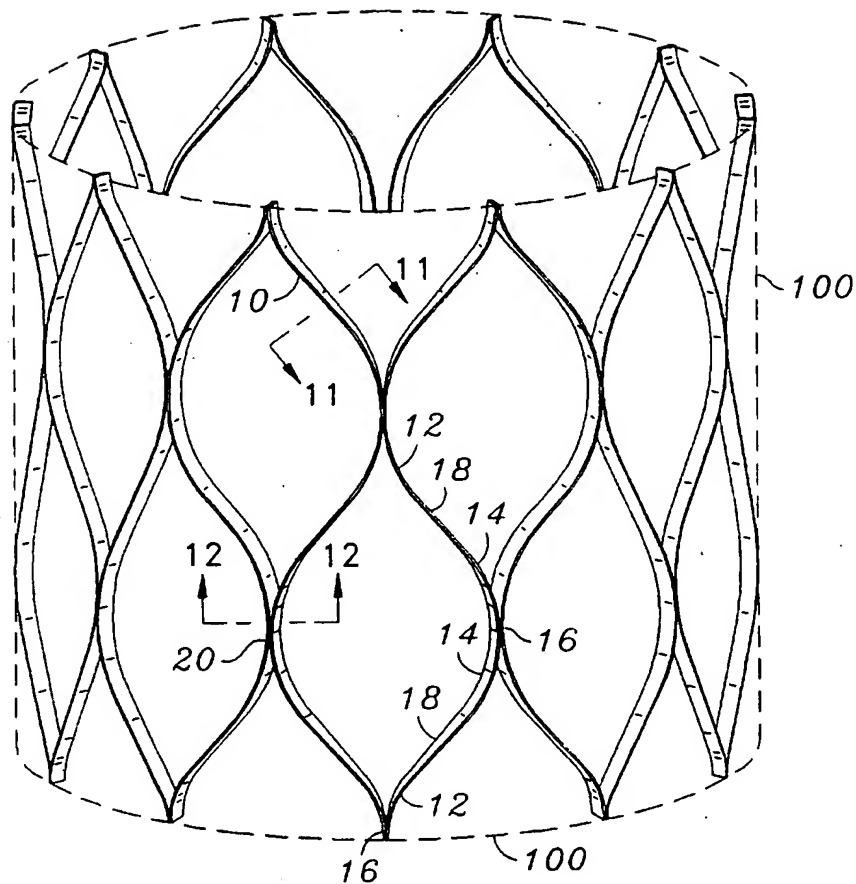


FIG. 10



FIG. 11

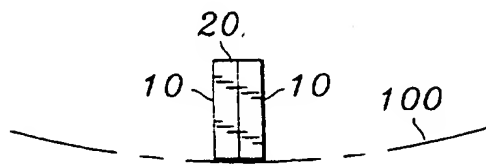


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/00033

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/04

US CL :623/1, 11, 12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/191, 192, 194, 195, 198; 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | US 5,476,508 A (AMSTRUP) 19 December 1995, Figs. 2, 3 and 6. | 1-6 |
| Y | US 4,214,587 A (SAKURA, JR.) 29 July 1980, col. 3, lines 67-68; and Fig. 1. | 7 |
| Y | US 5,423,885 A (WILLIAMS) 13 June 1995, col. 2, lines 17-21. | 8 |
| Y | US 5,192,307 A (WALL) 09 March 1993, col. 4, lines 25-39. | 9 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | |
|--|--|
| * Special categories of cited documents: | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" earlier document published on or after the international filing date | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Z" document member of the same patent family |
| "O" document referring to an oral disclosure, use, exhibition or other means | |
| "P" document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

02 MARCH 1997

Date of mailing of the international search report

31 MAR 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

JOHN M. BLACK

Telephone No. (703) 305-7341

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☒ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.